Anatomic Constraints for a Total Artificial Heart in Orthotopic Heart Transplant Recipients

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The anatomic constraints and design parameters for a heart prosthesis have not yet been defined in heart transplant recipients (i.e., the population most eligible for total artificial heart implantation). The parameters regarding anatomic constraints were measured in 26 consecutive patients undergoing orthotopic heart transplantation (median body surface area 1.9 m^2) after cardiectomy. A full-sized contour model of the cylindric total artificial heart (diameter 97 mm; width 81 mm) was inserted into the pericardial cavity to decide the pump configuration and to verify its fit. The dimensions of this model were based on the miniature electromechanical total artificial heart that is currently under development. Fit was found to be adequate in most of the cases with no identifiable compression of adjacent vascular structures. The median intraoperative measurements that define pericardial constraints for a heart prosthesis were pericardial length (130 mm), width (160 mm), and depth (140 mm). We also took measurements from the excised hearts, which should provide a useful reference for other prosthetic devices. The current dimensions of our implantable total artificial heart were found acceptable for orthotopic implantation. Length of the pericardium and cardiothoracic ratio were identified as variables related to adequacy of fit. J HEART LUNG TRANSPLANT 1994;13:250-62.

Total artificial hearts (TAH) have demonstrated clinical capabilities of profound circulatory assistance with substantial use during recent years.[1,2] The current increased use of the TAH began in 1982, when a Jarvik-7 TAH was implanted as a permanent device.[3,4] This case demonstrated that a patient could be supported for prolonged periods with a TAH. Also, TAHs have successfully been used to support transplant candidates with hemodynamically deteriorating conditions as a temporary device.[5,6] From 1985 to 1986, the Jarvik-7 was used as a bridge to transplantation in approximately 75% of all orthotopic implantations of mechanical devices.[7] TAHs including the Jarvik-7, were implanted in more than 200 patients.[2] These experiences have made dramatic improvements in patient survival, although many problems were encountered at the same time. Particularly, anatomic fit of the TAH is an important issue requiring extensive attention.

Anatomic constraints, especially regarding mediastinal fit of TAHs, have not received a great deal of attention during early stages of prosthetic heart development. One of the major problems was anatomic compatibility, even for the pneumatically driven TAH.[8,9] Some attempts have been made to quantify anatomic constraints in human cadavers for artificial hearts, but a limitation of cadaver studies was distortion of critical anatomic structures caused by tissue fixation.[9] Because of this postmortem shortcoming, computed tomography and nuclear magnetic resonance imaging were used to define intrathoracic dimension and identify critical cardiovascular structures to facilitate the design of various heart prostheses.[10,11] Anatomic constraints and

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design parameters for a heart prosthesis have not yet been defined in heart transplant recipients (i.e., the population most eligible for TAH implantation).

In 1988 a 70 cc stroke volume pump had been designed to meet National Institutes of Health criteria requiring resting cardiac output of 6 L/min and maximum output of 8 L/min.[12] However, this design was not practical for clinical application, particularly from an anatomic fit point of view. For implantation in the majority of patients, it was necessary to have further size reduction and therefore the stroke volume was reduced to 63 cc. The basic configuration of the cylindrically shaped pump body with unique cone-shaped pusher plates and housing was designed to allow the actuator components to be accommodated in the space between two blood chambers. The intensive anatomic study of this pump model was then performed in orthotopic heart transplant recipients because anatomic compatibility is one of the major issues that should be addressed for development of the clinically suitable TAH. The objectives of this study were (1) to obtain anatomic constraints inside the pericardial space for heart prostheses and (2) to verify the fit of the current pump model inside the pericardial space in orthotopic heart transplant recipients.

PATIENTS AND METHODS

Patients

Forty-six patients underwent orthotopic heart transplantation from February 1990 to February 1991 at the Methodist Hospital in Houston, Texas. These included 43 men and three women with a median age of 55 years (range 33 to 70 years). The cause of heart disease was ischemic heart disease (IHD) in 31 patients, idiopathic cardiomyopathy (ICM) in 14 patients and viral cardiomyopathy in one patient. All patients were heart transplant candidates showing New York Heart Association class IV. Of the 46 consecutive orthotopic heart transplant recipients, 26 were selected at random for this study. There were 25 men and one woman with a median age of 54 years (range 35 to 66 years). One patient had a Novacor left ventricular assist system (Baxter Healthcare Corp., Novacor Division, Oakland, Calif.) as a bridge to transplantation. Relevant data obtained included the following: age, sex, height, weight, body surface area, cause of underlying heart disease, and cardiothoracic ratio obtained from posteroanterior view of the upright chest x-ray film before transplantation. The causes of heart disease in the group studied were IHD in 18 patients and ICM in eight patients.

Intraoperative Measurements

Orthotopic heart transplantation was performed with the usual techniques.[13] Recipient ventricles were excised along the atrioventricular groove, staying within the atria, with the patient under cardiopulmonary bypass. After excision, both atria were trimmed for easy grafting of the donor heart. Both atrial appendages were resected. Then stay sutures were placed to get a good exposure of the surgical field. Before surgical anastomosis of the cardiac allograft, the following seven parameters were measured during surgery to define anatomic constraints inside the pericardium for a heart prosthesis: distance from the sternum to the center of the right and left atriotomies, the diameter of the right and left atriotomies, and the dimensions of the pericardium: length, from remnant aorta to inferior limit of pericardium; width, right lateral limit of pericardium to left lateral limit; and depth, sternum to posterior limit of pericardium. Measurements were done with a scale and calliper by one of the two surgeons (G.P.N. or M.E.S.).

Basic Pump Configuration and Multiadjustable Fitting Device

The blood pump being developed is electromechanically driven (i.e., motor driven) and one piece with a double-acting actuator that is sandwiched by left and right blood chambers (Figure 1). The basic pump body is cylindrically shaped with a diameter of 97 mm and a width of 81 mm. Two cone-shaped pusher plates and polyolefin rubber diaphragms allow appropriate space for mechanical and electrical components between these blood chambers. The designed stroke volume is 63 ml, with a full stroke of ½-inch displacement of the pusher plate. Hall-effect position sensors are incorporated to detect the stroke distance of the pusher plates. Twenty-seven and 23 mm bovine pericardial valves (Medtronic Cardioplumonary, Anaheim, Calif.) are incorporated in the inflow cuffs and 30 mm Dacron outflow grafts, respectively. A metal ring is mounted on each port of the pump and used for a slip-in connection.

A multiadjustable fitting device was constructed from the basic pump configuration with room-temperature vulcanizing silicone rubber (RTV). Its purpose was to verify gross anatomic fit and to define alignments of the four ports (Figure 2). This device has four malleable extensions with metal disks that are manipulated to match the aorta, pulmonary artery, and both atria. An inflow valve will be placed inside the port, and atrial disks are located 15 mm apart from the pump body to duplicate trimmed

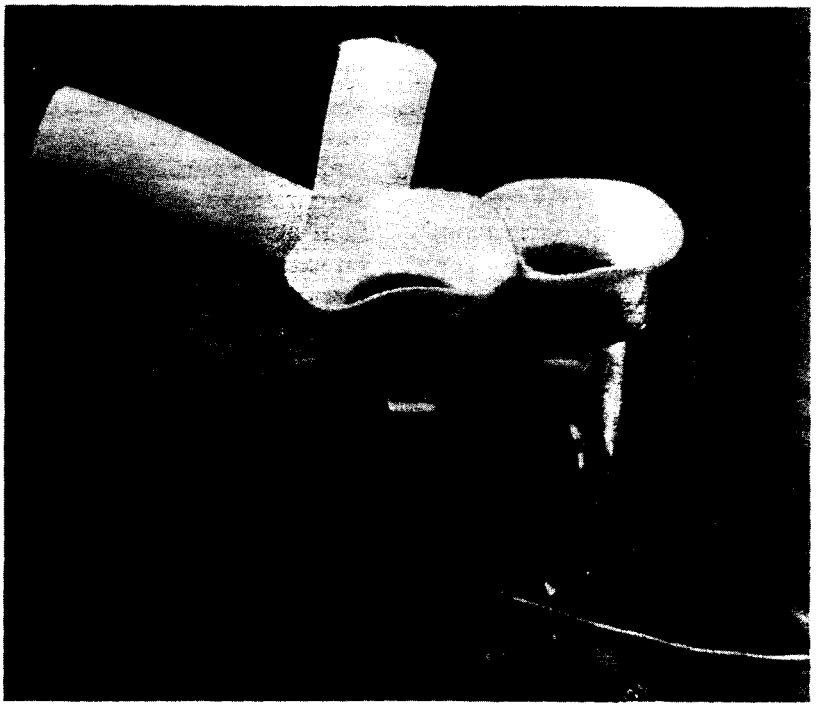

FIGURE 1 Prototype of electromechanical one-piece total artificial heart pump with atrial cuffs and outflow grafts.

atrial connecting cuffs. These extensions are malleable so that a smooth alignment between the pump ports and the remnant structures can be obtained. On completion of the basic study, a complete RTV rubber model was made incorporating 30 mm Dacron grafts for outflow and atrial cuffs for inflow to verify final anatomic fit (Figure 3).

Contour Model Fitting

After intraoperative measurements were made, the multiadjustable fitting device was inserted in the first 15 patients into the pericardial cavity through a median sternotomy wound with a retractor in place to verify anatomic fit (Figure 4). Both atrial connections were secured in place by bending the atrial extensions. After the arterial extensions were bent, the distal disks were inserted into the great arteries to get a smooth alignment between the remnant great arteries and each arterial extension. Conditions for satisfactory fit consisted of adequate pericardial fitting without compression of adjacent vascular structures. In the fit-verification study of the complete RTV model of the TAH, both atrial connecting cuffs had been trimmed 5 to 10 mm in width circumferentially before surgery according to TAH implant technique.[14] A complete RTV model was inserted in the next 11 patients. Special attention was paid to examine compression (deformities, excess expansions, and kinking) of both atria, superior and inferior vena cava, and kinking of the great arteries. Ease of insertion and extraction of the pericardium were also examined. The fitting status was classified into four categories: (1) excellent fit, no compression of adjacent structure; (2) good fit, easy to insert, slight misalignment of the great arteries; (3) tight fit, tight to insert, compression of the atrium; and (4) impossible to insert. After examining the fitting status, the donor heart was grafted to the native remnant structures for standard orthotopic heart transplantation.

Measurements of Excised Heart

Measurements consisting of 12 distances and two angles were obtained from the excised heart on which the fundamental design of a TAH could be based. The following parameters were measured: diameters of four valve annuli and both atriotomy orifices, distances between two major structures,

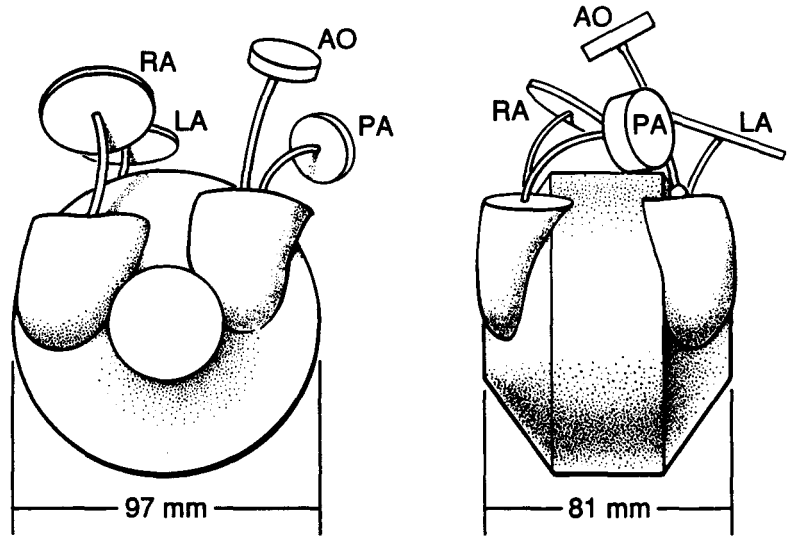

FIGURE 2 Multiadjustable fitting device constructed from basic pump configuration with room-temperature vulcanizing silicone rubber. *RA,* Right atrial; *LA,* left atrial; *PA,* pulmonary arterial; *AO,* aortic.

and two angles: angle α, formed by the intersection of lines extending from the centers of the pulmonary and aortic valves and the centers of the mitral and tricuspid valves, and angle β, formed between the left and right atrial orifices. The excised heart was held manually while its shape was kept as natural as possible and measured with scale and caliper within 1 hour after excision.

Statistical Analysis

Measured data are reported as percentiles because the data were not distributed normally. For comparison of patients studied with the non-studied patients undergoing transplantation during the same period, *p* values were computed with the Wilcoxon rank-sum test for numeric variables and the Pearson chi-squared test for the cause. For comparison of patients with ICM and IHD, *p* values were computed by the Wilcoxon rank-sum test and confidence intervals for the median values were computed by the exact method based on the binomial distribution. Concerning fitting status, univariate logistic regression was used initially to identify variables related to adequacy of fit. Multiple logistic regression was used to assess the simultaneous classification abilities of the variables. Analyses were performed with the BMDP statistical software package (BMDP Statistical Software Inc., Los Angeles, Calif.) and the Confidence Interval Analysis program.

FIGURE 3 Finalized configuration of pump made from room-temperature vulcanizing silicone rubber with cuffs and grafts.

RESULTS

Comparison of age, height, weight, body surface area, and cause among the 26 patients included in the study and 20 additional patients who also underwent orthotopic heart transplantation during

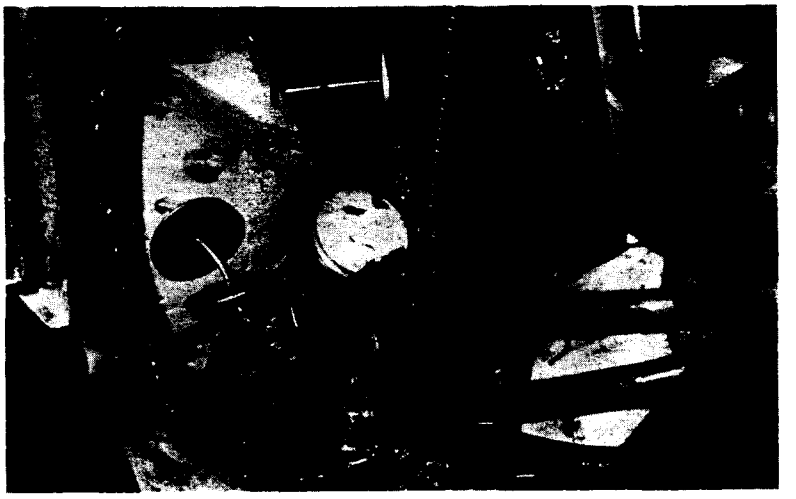

FIGURE 4 Intraoperative fitting evaluation with multiadjustable device. See text for fitting method.

TABLE I Characteristics of 26 patients

Variable	Min	25th P	50th P	75th P	Max
Age (yr)	35	50	56	61	70
Height (cm)	155	170	178	183	190
Weight (kg)	67.0	70.8	76.5	82.2	120.0
CTR (%)	49.0	53.5	55.5	60.0	69.0
BSA (m^2)	1.7	1.8	1.9	2.1	2.4

Min, Minimum; *P,* percentile; *Max,* maximum; *CTR,* cardiothoracic ratio; *BSA,* body surface area.

TABLE II Comparison of patients with ICM and IHD

	ICM (8 patients)		IHD (18 patients)		
Variable	Median	95% CI	Median	95% CI	*p* Value*
Age (yr)	54.5	35, 66	56.0	52, 60	0.76
Height (cm)	174	155, 190	180	173, 183	0.85
Weight (kg)	73.5	67, 83	79.5	72, 83	0.18
CTR (%)	58.5	54, 69	55.0	51, 58	0.089
BSA (m^2)	1.9	1.8, 2.2	2.0	1.8, 2.1	0.19
STRA (mm)	75	60, 120	80	70, 100	0.83
STLA (mm)	115	90, 160	115	90, 140	0.85
Diameter RA (mm)	59	45, 72	50	50, 65	0.19
Diameter LA (mm)	60	45, 70	50	50, 60	0.16
AOIP (mm)	120	80, 140	140	120, 150	0.063
PW (mm)	150	130, 180	160	150, 180	0.32
STPP (mm)	150	110, 170	132	120, 150	0.21

ICM, Idiopathic cardiomyopathy; *IHD,* ischemic heart disease, *CI,* confidence interval; *CTR,* cardiothoracic ratio; *BSA,* body surface area; *STRA,* distance from sternum to center of right atriotomy; *STLA,* distance from sternum to center of left atriotomy; *RA,* right atriotomy; *LA,* left atriotomy; *AOIP,* distance from remnant aorta to inferior limit of pericardium (length); *PW,* right lateral limit of pericardium to left lateral limit (width); *STPP,* sternum to posterior limit of pericardium (depth).
*Wilcoxon rank-sum test.

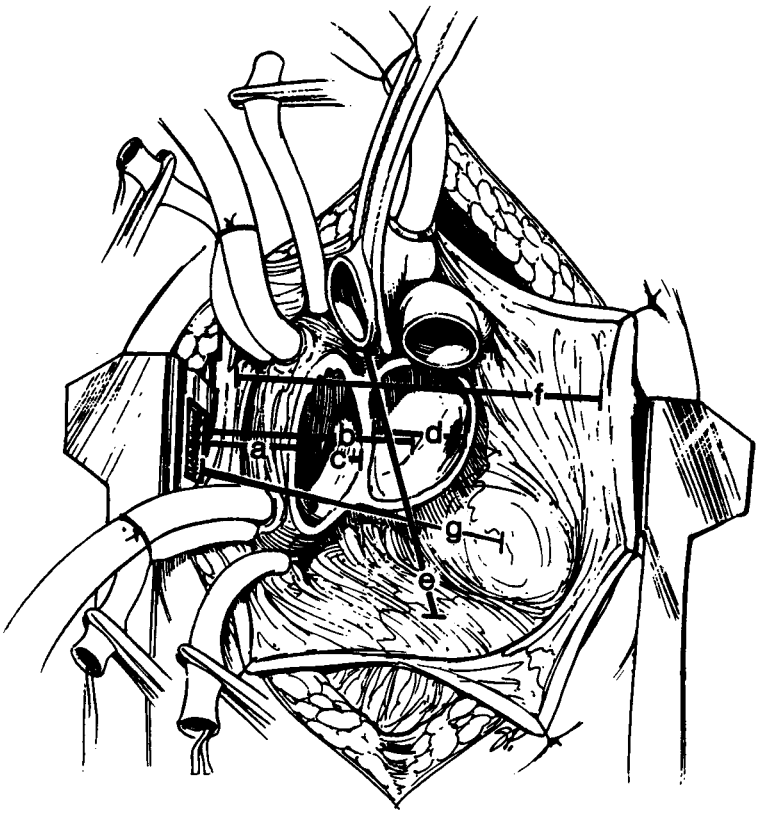

FIGURE 5 Cardiectomized pericardial cavity with dimensions. *a,* Sternum to center of right atriotomy; *b,* sternum to center of left atriotomy; *c,* diameter of right atriotomy; *d,* diameter of left atriotomy; *e,* remnant aorta to inferior limit of pericardium; *f,* right lateral limit of pericardium to left lateral limit; *g,* sternum to posterior limit of pericardium.

TABLE III Intraoperative measurements of 26 patients

Variable	Min	25th P	50th P	75th P	Max
STRA (mm)	50	70	80	100	130
STLA (mm)	80	95	115	139	170
Diameter RA (mm)	40	50	50	64	72
Diameter LA (mm)	45	50	55	60	70
AOIP (mm)	80	110	130	150	170
PW (mm)	110	150	160	180	200
STPP (mm)	110	120	140	150	170

Min, Minimum; *P,* percentile; *Max,* maximum; *STRA,* distance from sternum to center of right atriotomy; *STLA,* distance from sternum to center of left atriotomy; *RA,* right atriotomy; *LA,* left atriotomy; *AOIP,* distance from remnant aorta to inferior limit of pericardium (length); *PW,* right lateral limit of pericardium to left lateral limit (width); *STPP,* sternum to posterior limit of pericardium (depth).

the same period indicated no obvious selection bias. The morphometric data are listed in Table I. The patients' median age was 56 years, height 178 cm, weight 76.5 kg, cardiothoracic ratio 55.5%, and body surface area 1.9 m^2. The cause of heart disease was IHD in 18 patients and ICM in eight patients. Comparison related to cause of diseases did not show statistical differences in morphometric variables (Table II).

The intraoperative measurements obtained are listed in Table III. The median values of measurements are as follows: the dorsoventral height from

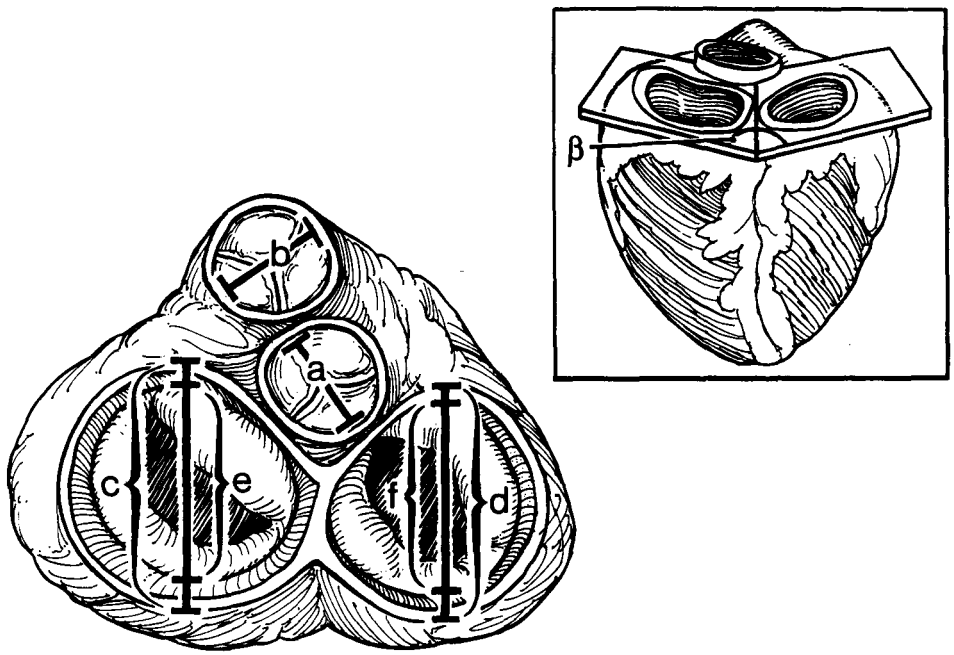

FIGURE 6 Dimensions obtained from excised heart (diameters). *a,* Aortic valve; *b,* pulmonary valve; *c,* left atrial orifice; *d,* right atrial orifice; *e,* mitral valve; *f,* tricuspid valve; *β,* angle β.

TABLE IV Measurements of excised hearts in 15 patients

Measurement	Min	25th P	50th P	75th P	Max
AV diameter (mm)	22.0	25.0	27.5	30.0	36.0
PV diameter (mm)	22.0	25.5	29.0	33.5	38.0
MV diameter (mm)	30.0	32.0	33.0	35.0	40.0
TV diameter (mm)	28.0	35.0	36.0	38.0	40.0
Left atrial orifice (mm)	36.0	40.0	42.0	48.5	52.0
Right atrial orifice (mm)	38.0	45.0	47.0	49.0	55.0
MV to posterior surface (mm)	35.0	40.0	42.0	45.0	45.0
MV to AV (mm)	32.0	35.0	39.5	44.5	55.0
PV to AV (mm)	25.0	28.0	31.0	34.0	35.0
PV to TV (mm)	50.0	55.0	60.0	63.0	67.0
TV to posterior surface (mm)	25.0	35.0	55.0	55.0	70.0
TV to MV (mm)	45.0	49.0	51.5	54.0	62.0
Angle α (degree)	60.0	75.0	79.0	80.0	85.0
Angle β (degree)	135.0	155.0	160.0	166.0	170.0

Min, Minimum; *P,* percentile; *Max,* maximum; *AV,* aortic valve; *PV,* pulmonary valve; *MV,* mitral valve; *TV,* tricuspid valve.

the sternum to the center of the right and left atriotomies (right 80 mm; left 115 mm), the diameters of right and left atriotomies (right 50 mm; left 55 mm), and the pericardial dimensions (length 130 mm, width 160 mm, and depth 140 mm) (Figure 5).

The parameters measured from the first 15 excised native hearts are listed in Table IV. The median values of the diameters in each dimension were as follows: aorta 27.5 mm, pulmonary artery 29 mm, mitral valve orifice 33.0 mm, tricuspid valve orifice 36.0 mm, right atriotomy 47.0 mm, and left atriotomy 42.0 mm) (Figure 6). Median distances between each valve were 39.5 mm in mitral valve to aortic valve, 31.0 mm in pulmonary valve to aortic

valve, 60.0 mm in pulmonary to tricuspid valve, and 51.5 mm in tricuspid to mitral valve (Figure 7). Distances from the mitral valve and the tricuspid valve to the posterior surface of the excised heart were 42.0 mm and 55.0 mm, respectively. Angle α is formed by the intersecting lines extending from the centers of the pulmonary and aortic valves, and the centers of the mitral and tricuspid valves were 79.0 degrees. Angle β, formed between the right and left atriotomy orifices, was 160.0 degrees.

The fitting status of the multiadjustable device in these 15 patients is described in Table V. Thirteen patients showed excellent or good fit (class I or II), and in two patients remnant atria or inferior vena cava were compressed by the device and showed a tight fit (class III). With the complete RTV TAH model, configuration of the pump was finalized through the fit-verification study, which showed class I or II in 11 patients (Table VI). Five patients (45%) had class I and six (55%) had class II fit. Univariate logistic regression identified remnant aorta to inferior limit of pericardium ($p = 0.0058$), cardiothoracic ratio ($p = 0.066$), and cause ($p = 0.026$) as the only variables related to adequacy of fit (class I versus class II). Of these three, multiple logistic regression identified only remnant aorta to inferior limit of pericardium as an independent predictor of class of fit.

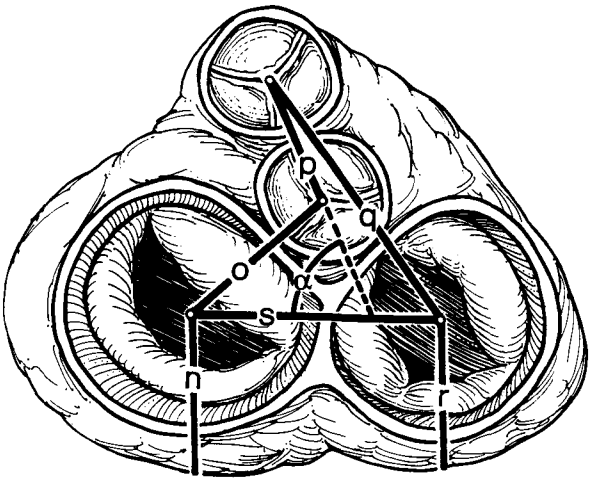

FIGURE 7 Dimensions obtained from excised heart (distances). *n*, Center mitral valve to posterior surface; *o*, center mitral to center aortic valve; *p*, center aortic to center pulmonary valve; *q*, center pulmonary to center tricuspid valve; *r*, center tricuspid valve to posterior surface; *s*, center mitral to center tricuspid valve; *α*, angle α.

DISCUSSION

During the last 30 years in the development of TAH, one of the major problems was its anatomic compatibility, even in the pneumatically driven TAH.[8,9] The successful Jarvik-7 TAH was introduced clinically based on its excellent anatomic compatibility. The Jarvik-7 TAH is a pneumatically driven pump consisting of two separate ventricles with an external-drive console.[15] This device was designed in 1977 based on human anatomic considerations, with fitting trials performed on human cadavers to evaluate the shape and design modifications.[16] In 1982 Kolff et al.[15] performed implantations of the Jarvik-7-100, which had a 100 cc stroke volume in five human brain-dead cadavers to assess anatomic positioning. In a surgical positioning study of 18 patients receiving the Jarvik-7, complications related to positioning were a contributing factor to patients' survival. The initially introduced Jarvik-7-100 was considered to be too large for an average-size patient. A smaller Jarvik-7-70, which had a stroke volume of 70 cc, was introduced later and implanted in patients with a body surface area less than 2 m^2 to minimize complications associated with mismatch of anatomic size(i.e., atrial compression and vena caval kinking). The Jarvik-7-70 was considered to be anatomically compatible for the majority of the patients and was implanted in a substantial number of patients.[2,17-20]

However, many problems were encountered with the two-piece or partially implantable pumps (e.g., high risk of infection and the tethered life-style). The majority of the clinical TAHs were partially implantable systems with the ventricles implanted orthotopically and the driving unit placed extracorporeally. The major problem is the high risk of infectious complications after a long-term support associated with transcutaneous drive lines that also limit the life-style for patients tethered to an external power console. Device-centered infection is an important problem, especially in patients with TAHs.[21,22] It is hypothesized that a volumetrically compliant pump like the Jarvik-7 causes continuous mechanical stress on tissues around the device. This two-piece pump has a large dead space around the two ventricles and pericardium and provides culture media for microorganisms. The pump has to be anatomically compatible and should not allow excess dead space inside the body to avoid these infectious complications.

Because of these problems, the development of a totally implantable TAH is necessary. During the

TABLE V Fitting status of multiadjustable fitting device in 15 patients

Patient	Date	Age (yr)	Gender	Height (cm)	Weight (kg)	CTR (%)	BSA (m^2)	Status
1	Feb. 10, 1990	44	M	175	72	55	1.88	II
2	Feb. 18, 1990	54	M	173	81	62	1.96	II
3	Feb. 26, 1990	35	M	180	83	65	2.04	I
4	March 5, 1990	64	M	178	73	52	1.85	I
5	March 14, 1990	50	M	180	95	49	2.20	I
6	March 15, 1990	65	M	178	75	54	1.90	II
7	March 24, 1990	42	M	170	79	57	1.94	II
8	March 28, 1990	59	M	165	68	60	1.77	II
9	April 16, 1990	49	M	183	81	50	2.06	I
10	April 18, 1990	54	M	183	82	51	2.10	II
11	May 4, 1990	66	M	173	76	55	1.90	I
12	June 3, 1990	62	M	183	72	58	1.92	I
13	June 6, 1990	60	M	183	83	55	2.06	I
14	June 22, 1990	45	F	155	70	60	1.85	III
15	July 19, 1990	51	M	180	73	51	1.93	III

See text for definition of fitting status. *CTR*, Cardiothoracic ratio; *BSA*, body surface area.

TABLE VI Fitting status in verification study of 11 patients

Patient	Date	Age (yr)	Gender	Height (cm)	Weight (kg)	CTR (%)	BSA (m^2)	Status
16	Aug. 17, 1990	59	M	183	90	55	2.12	I
17	Aug. 30, 1990	55	M	178	120	54	2.40	II
18	Sept. 5, 1990	70	M	160	68	54	1.74	II
19	Sept. 11, 1990	59	M	180	70	62	1.93	II
20	Sept. 24, 1990	53	M	165	77	56	1.85	II
21	Oct. 16, 1990	52	M	186	98	49	2.28	II
22	Nov. 21, 1990	57	M	178	80	58	1.97	II
23	Dec. 7, 1990	59	M	190	79	69	2.15	I
24	Feb. 6, 1991	60	M	178	68	63	1.84	I
25	Feb. 12, 1991	64	M	168	67	59	1.77	I
26	Feb. 13, 1991	50	M	170	71	58	1.83	I

See text for definition of fitting status. *CTR*, Cardiothoracic ratio; *BSA*, body surface area.

development of a totally implantable system that incorporates an actuation mechanism, control system, and power source, additional anatomic problems may be encountered. The properly designed pump will not compress the soft adjacent tissues, especially the venous system. A one-piece pump eliminates the dead space between the two ventricles and also optimizes the pumping efficiency. Totally implantable systems also eliminate drive lines, which can be an origin of infections and require a tethered life-style. An electromechanical drive system, which was a simpler and safer mechanism, was selected. The left-master-alternate mode of pumping was selected as a control method of the Baylor TAH to maintain left atrial pressure within physiologic range.[23,24] This mode of actuation also allows further size reduction of a TAH. The pericardial space was chosen as the primary position for the pump to minimize fitting problems and simplify implanting techniques without the necessity of additional pericardiectomy.

Preliminary attempts were performed to quantify anatomic constraints in animals and human cadavers for implantation of artificial hearts.[9] However, there are many limitations encountered in cadaver studies that lead to distortion of critical anatomic

structures caused by postmortem tissue fixation, such as lung deflation, elevation of diaphragm, and myocardial deformity. Availability of fresh cadavers that have end stage heart disease in New York Heart Association class IV and transplant candidates that are currently the target population for TAH implants are limited. It is not desirable to use a stored cadaver for a device-fitting study because an accurate fitting condition of the device cannot be obtained. Because of these postmortem shortcomings, computed tomography and nuclear magnetic resonance imaging were used in patients to define intrathoracic dimension and identify critical cardiovascular structures to facilitate the design of various heart prosthetic devices.[10,11,25] Most of these data are not necessarily useful for the designing phase of the TAHs. At the present time it has not been defined what the critical and important dimensions for TAHs are and which parameters might be useful. This study was conducted to decide the pump configuration and to verify the anatomic fitting of the Baylor TAH, as well as to define anatomic constraints for any heart prosthesis. The data obtained here are expected to provide an idea of the constraints for designing a heart prosthesis. Data sets obtained in this target population of TAHs have not been reported previously.

Our morphometric data and intraoperatively measured data are expected to be representative of the target population of current TAH implants. These data are available for patients with both IHD and ICM. The intraoperative measurements obtained define the intrathoracic and pericardial anatomic constraints available for a heart prosthesis. The pericardial measurements (median length 130 mm, width 160 mm, and depth 140 mm) give an estimate of the global dimensions available. The diameters of the right and left atriotomies, where surgical anastomoses will be made with the inflow cuffs of the TAH, provide an appropriate size needed for the inflow cuffs (median right diameter 50 mm; left diameter 55 mm). The most relevant dimension is the length of the pericardium between the remnant aorta and inferior limit of pericardium according to our fit-verification study. Cardiothoracic ratio is also a relevant dimension. Larger devices displace the atria and compress or occlude the vena cavae and the hilar structures.[15] The mechanical devices that extend beyond the pericardium need additional pericardiectomy and may cause compression of the left lung and pulmonary hilus or palsy of the diaphragm. This can result in decreasing volumes and lung damage.

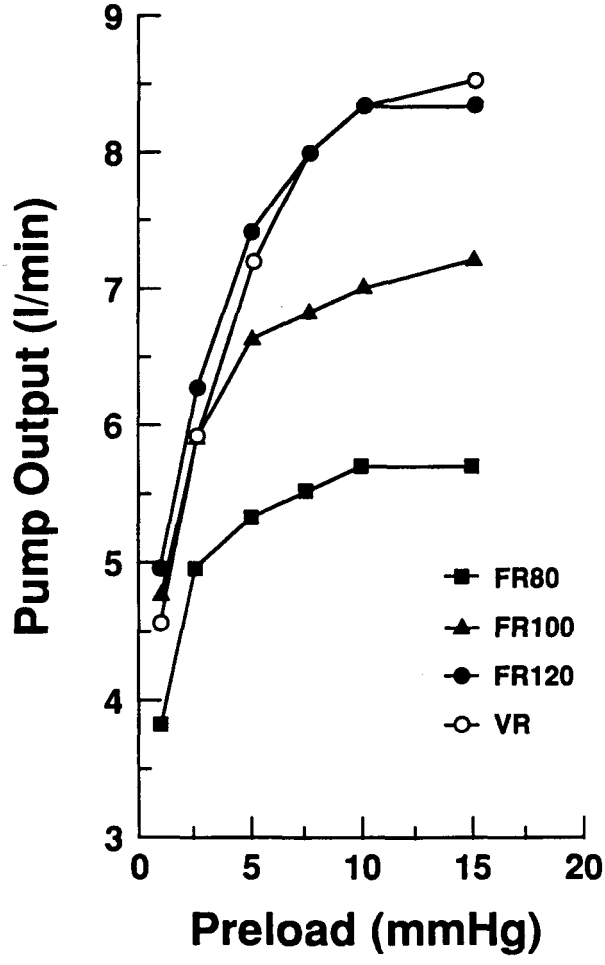

FIGURE 8 In vitro performance curve of electromechanical TAH. *FR,* Fixed rate (beats per minute); *VR,* variable rate.

A multiadjustable fitting device was made to verify gross anatomic fit and to define the alignments of four ports in the first phase. The insertion of the multiadjustable device during surgery verified gross anatomic fitting of the size-reduced TAH inside the pericardial space. The pericardial cavity was demonstrated to be sufficiently large in this population of patients, with no detectable compression of adjacent anatomic structures. The alignment of the outflow and inflow ports to their respective anastomotic points (atriotomies and great arteries) was examined. A fine and smooth alignment between the pump ports and the remnant structures was obtained with these malleable extensions. This information was used to modify the position and angulation of both inflow and outflow ports for minimizing the chances of compression or kinking of the

TABLE VII Entire measured data in 15 patients

	Patient No.											
	1	2	3	4	5	6	7	8	9	10	11	12
Date (1990)	Feb. 10	Feb. 18	Feb. 26	March 5	March 14	March 15	March 24	March 28	April 16	April 18	May 4	June 3
Age (yr)	44	54	35	64	50	65	42	59	49	54	66	62
Gender	M	M	M	M	M	M	M	M	M	M	M	M
Height (cm)	175	173	180	178	180	178	170	165	183	183	173	183
Weight (kg)	72	81	83	73	95	75	79	68	81	82	76	72
CTR (%)	55	62	65	52	49	54	57	60	50	51	55	58
BSA (m^2)	1.88	1.96	2.04	1.85	2.20	1.90	1.94	1.77	2.06	2.10	1.90	1.92
Cause	ICM	IHD	ICM	IHD	IHD	ICM	IHD	IHD	IHD	IHD	ICM	IHD
STRA	60	NA	120	90	100	100	60	50	75	NA	70	70
STLA	90	NA	150	130	150	120	80	80	90	NA	110	110
Diameter RA	60	NA	70	50	50	55	60	48	65	NA	58	50
Diameter LA	45	NA	60	50	55	55	50	55	60	NA	63	45
AOIP	90	NA	>170	130	120	140	110	150	170	NA	130	150
PW	140	NA	>180	160	150	130	150	160	180	NA	150	160
STPP	140	NA	>150	120	110	170	130	130	120	NA	110	120
Diameter AV	35	25	NA	25	30	36	27	25	28	NA	22	NA
Diameter PV	32	34	NA	30	28	35	30	22	25	NA	27	NA
Diameter MV	35	33	NA	33	32	36	32	35	32	NA	30	43
Diameter TV	37	38	NA	36	36	38	36	40	40	NA	28	35
LA orifice	42	36	NA	50	42	44	40	40	50	NA	36	51
RA orifice	43	55	NA	55	48	52	47	45	49	NA	38	48
MV to posterior surface	42	43	NA	45	40	40	42	35	45	NA	40	45
MV to AV	38	40	NA	34	39	38	43	40	55	NA	45	NA
PV to AV	35	30	NA	30	28	32	34	25	25	NA	28	NA
PV to TV	63	60	NA	50	58	65	62	60	55	NA	55	NA
TV to posterior surface	60	55	NA	70	60	55	55	25	40	NA	35	43
TV to MV	54	50	NA	55	53	52	51	50	49	NA	45	55
Angle α (degree)	75	80	NA	60	78	80	78	78	83	NA	85	NA
Angle β (degree)	157	163	NA	135	166	166	137	156	160	NA	160	165

All values expressed in millimeters unless otherwise noted. *CTR,* Cardiothoracic ratio; *BSA,* body surface area; *STRA,* distance from sternum to center of right atriotomy; *STLA,* distance from sternum to center of left atriotomy; *RA,* right atriotomy; *LA,* left atriotomy; *AOIP,* distance from remnant aorta to inferior limit of pericardium (length); *PW,* right lateral limit of pericardium to left lateral limit (width); *STPP,* sternum to posterior limit of pericardium (depth); *AV,* aortic valve; *PV,* pulmonary valve; *MV,* mitral valve; *TV,* tricuspid valve.

inflow and outflow tracts. Configuration of the pump was finalized through the fit-verification study, which showed class I or II in all patients. Cardiothoracic ratio and remnant aorta and inferior limit of pericardium were identified as variables related to adequacy of fit individually, through univariate analysis (remnant aorta and inferior limit of pericardium more so than cardiothoracic ratio). Given remnant aorta and inferior limit of pericardium, cardiothoracic ratio did not improve the classification significantly.

The entire measured data are shown because the data set obtained was fairly small (Table VII). A limitation of this study was that we were able to measure and assess only anatomic fit of the TAH model with the chest open (with sternal retractors in place). To compensate partially for this inaccuracy, we also measured the dimensions of the excised

Patient No.													
13	14	15	16	17	18	19	20	21	22	23	24	25	26
June 6	June 22	July 19	Aug. 17	Aug. 30	Sept. 5	Sept. 11	Sept. 24	Oct. 16	Nov. 21	Dec. 7	Feb. 6, 1991	Feb. 12, 1991	Feb. 13, 1991
60	45	51	59	55	70	59	53	52	57	59	60	64	50
M	F	M	M	M	M	M	M	M	M	M	M	M	M
183	155	180	183	178	160	180	165	186	178	190	178	168	170
83	70	73	90	120	68	70	77	98	80	79	68	67	71
55	60	51	55	54	54	62	56	49	58	69	63	59	58
2.06	1.85	1.93	2.12	2.40	1.74	1.93	1.85	2.28	1.97	2.15	1.84	1.77	1.83
IHD	IHD	ICM	IHD	IHD	IHD	IHD	IHD	IHD	IHD	ICM	IHD	ICM	ICM
80	60	90	115	70	50	120	130	90	80	80	80	110	70
95	95	120	170	110	80	135	140	120	140	120	110	160	100
50	45	44	65	50	40	70	50	50	70	72	50	60	50
50	50	50	60	50	50	70	55	50	70	70	50	70	60
140	110	125	120	140	150	160	145	150	110	110	120	120	80
160	140	110	200	140	150	180	170	160	200	180	160	180	160
140	130	150	150	135	150	120	150	140	160	150	130	150	160
35	23	29											
38	25	27											
40	33	34											
35	35	35											
52	40	42											
47	45	45											
45	45	40											
48	33	32											
35	35	33											
64	54	67											
34	45	55											
60	48	62											
73	80	82											
168	170	155											

heart. Another limitation was in keeping the shape of the excised heart as natural as possible. Once the heart is excised and the blood drained, that heart collapses and it is difficult to keep its natural shape as it was in the pericardial space. However, the data set obtained in this study is expected to be useful for understanding the dimensions of the available pericardial cavity and the failing heart in this specific population. Adequate anatomic constraints under such conditions could be estimated by designing a three-dimensional model of the pericardial or intrathoracic cavity. The developed one-piece TAH was found to be implantable in all cases in this study. The current dimensions are acceptable for orthotopic implantation, with no size modifications required at this time.

The electromechanical TAH with finalized configurations has been implanted in several calves weighing 80 to 90 kg without compression of adjacent structures and without additional pericardiectomy. In vitro and in vivo test results of this current TAH pump were verified to meet the flow requirements specified by the National Institutes of Health (Figure 8).[26,27] This system can be useful for future studies of the TAH and is expected to be useful as a bridge to transplantation, long-term

assistance, or permanent device for terminal patients with heart disease.

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